

# Paravertebral nerve blocks for analgesia after cardiac surgery

<b>Submission date</b> 10/07/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/07/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/06/2017	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The aim of this study is to find out whether injecting a local anaesthetic into the back to block the nerves to the chest (a paravertebral injection) reduces pain after cardiac surgery. This is a technique of pain control the trialists have been using recently and it sounds sensible, but it's hard to be sure that it really works because there are such big differences in the amount of pain people experience after cardiac surgery. What's more, just getting local anaesthetics into the blood stream reduces pain after other surgical operations, so it may be that paravertebral injections are working simply because the drug is being absorbed into the blood. This study is designed to clarify the situation.

### Who can participate?

Patients undergoing coronary artery bypass grafting.

### What does the study involve?

Patients are randomly allocated into one of two groups. Those in group 1 are given bilateral paravertebral blocks during surgery. Those in group 2 are given a dummy, or 'sham', injection under the skin. After surgery, patients are able to self-administer pain relief (morphine) as they need it, to see whether the patients with true paravertebral injections want less morphine than those with the sham injections.

### What are the possible benefits and risks of participating?

It is hoped that all patients taking part get additional benefit from the local anaesthetic infusion. The catheters are placed under the same rigorous aseptic conditions as the rest of their surgery so no infections are expected.

### Where is the study run from?

Hammersmith Hospital (UK)

### When is study starting and how long is it expected to run for?

October 2014 to September 2016

Who is funding the study?  
Imperial College Healthcare NHS Trust (UK)

Who is the main contact?  
Dr Geoff Lockwood  
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## Contact information

**Type(s)**  
Public

**Contact name**  
Dr Geoff Lockwood

**ORCID ID**  
<https://orcid.org/0000-0003-3180-5824>

**Contact details**  
Hammersmith Hospital  
London  
United Kingdom  
W12 0HS

## Additional identifiers

**Protocol serial number**  
13HH1841

## Study information

**Scientific Title**  
A double blind, randomised controlled trial to assess the efficacy of bilateral paravertebral blockade for analgesia after cardiac surgery

**Study objectives**  
Do paravertebral blocks provide useful analgesia by blocking specific nerves or are we simply seeing the systemic effects of the local anaesthetics as they are absorbed into the circulation?

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
London (Dulwich), 08/08/2014, ref: 14/LO/0864

**Primary study design**  
Interventional

**Study design**

Single centre interventional randomised controlled trial

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Postoperative pain

### **Interventions**

Bilateral paravertebral blockade or sham infusion of lidocaine

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

Morphine consumption using a PCA device

### **Key secondary outcome(s)**

1. Pain (measured using ordinal scale) and respiratory function (PEFR) for first 7 days
2. Quality of life, measured using the EuroQol EQ-5D questionnaire at 3 months

### **Completion date**

14/09/2016

## **Eligibility**

### **Key inclusion criteria**

1. Age 40-70 years
2. Undergoing elective and urgent first time coronary bypass surgery

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **Key exclusion criteria**

1. Critical preoperative state
2. Single graft surgery (no leg incision)
3. Minimally invasive surgery (no sternotomy)
4. Significant renal disease (baseline creatinine >150 micromolar: morphine contraindicated)
5. Patients exceeding 110kg (4% of our operative population practical difficulties of positioning unconscious patients to place the block)
6. Pregnancy

7. Patients with chronic pain taking regular analgesic medication
8. Patients with a significant abnormality of coagulation
9. Participation in another interventional study
10. Patients unable to give informed consent
11. Hypersensitivity to lidocaine

**Date of first enrolment**

26/10/2014

**Date of final enrolment**

07/09/2016

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre****Hammersmith Hospital**

Ducane Road

London

United Kingdom

W12 0HS

## Sponsor information

**Organisation**

Imperial College Healthcare

**ROR**

<https://ror.org/056ffv270>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Imperial College Healthcare NHS Trust

**Alternative Name(s)**

Imperial NHS, imperialnhs, Imperial College Healthcare NHS Trust | London

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/10/2017		Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No